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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,413		Hyo-Joon Kim	0220.00002	1247
7590		10/02/2009		
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			EXAMINER	
			PENG, BO	
			ART UNIT	PAPER NUMBER
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			10/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,413	Applicant(s) KIM, HYU-JOON	
	Examiner BO PENG	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2008 and 13 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply and seq alignment</u> |

DETAILED ACTION

Restriction election

1. Applicant's election of Group I (Claims 1-12), and hybrid polypeptide SEQ ID NO: 9, in the reply dated December 12, 2008, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Upon further consideration the scope of the species, the examiner has decided to extend the search to all cited SEQ ID NO: in Claims 1-11. The species election set forth in the restriction requirement is withdrawn. Accordingly, Claims 1-15 are pending. Claims 12-15 are withdrawn from further consideration by the Examiner, under 37 CFR 1.142(b), as being directed to a nonelected invention. Claims 1-11 are examined in this Office action.

Response to Amendment

3. The new sequence listing and CRF filed February 13, 2009, are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The SEQ ID NO: 9 is not the same as originally filed in PCT/KR05/00784 (WO2005087800-A1), as evidenced by the sequence alignment below. Applicant is required to cancel the new matter in the reply to this Office Action.

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ID      AEC83141 standard; protein; 147 AA.
XX
XX
AC      AEC83141;
XX
XX
DT      01-DEC-2005 (first entry)
XX
XX
DE      Hybrid of apo B-100 B cell epitope and helper T cell epitope, seqid 9.
XX
XX
KW      immune stimulation; fusion protein; vaccine; obesity; anorectic;
KW      nutritional disorder.
XX
XX
OS      Chimeric.
OS      Unidentified.
XX
XX
PN      WO2005087800-A1.
XX
XX
PD      22-SEP-2005.
XX
XX
PF      18-MAR-2005; 2005WO-KR000784.
XX
XX
PR      18-MAR-2004; 2004KR-00018551.
XX
XX
PA      (SJB I-) SJ BIOMED INC.
XX
XX
PI      Kim H;
XX
XX
DR      WPI; 2005-639162/65.
DR      N-PSDB; AEC83140.
XX
XX
PT      New immunogenic hybrid polypeptide in which a C-terminus of a peptide is
PT      fused to an N-terminus of a helper T cell epitope, useful in preparing a
PT      vaccine for treating or preventing obesity.
XX
XX
PS      Claim 10; SEQ ID NO 9; 80pp; English.
XX
XX
SQ      Sequence 147 AA;

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Query Match      86.7%;   Score 794.5;   DB 2;   Length 147;
Best Local Similarity 89.0%;
Matches 146;   Conservative 0;   Mismatches 1;   Indels 17;   Gaps 1;

Qy      1 MRGSHHHHHHGSDDDDLIVDRNVPPPIFNDVYWIAFLDRNVPPPIFNDVYWIAFLDRNVPPI 60
      |||||
Db      1 MRGSHHHHHHGSDDDKIV-----DRNVPPPIFNDVYWIAFLDRNVPPI 43

Qy      61 FNDVYWIAFLDRNVPPPIFNDVYWIAFLDRNVPPPIFNDVYWIAFLDMQWNSTTFHQALLDP 120
      |||||
Db      44 FNDVYWIAFLDRNVPPPIFNDVYWIAFLDRNVPPPIFNDVYWIAFLDMQWNSTTFHQALLDP 103

Qy      121 RVRGLYFPAGGSSSGTVNPVPTTASPISSIFSRGTGDPAPNRLRS 164
      |||||
Db      104 RVRGLYFPAGGSSSGTVNPVPTTASPISSIFSRGTGDPAPNRLRS 147

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4. Applicant is required to re-submit a sequence listing, CRF and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821 (e) or 1.821 (f) or 1.821 (g) or 1.825(b) or 1.825(d). See attached Notice to Comply.

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Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim is recited below:

Claim 1: An immunogenic hybrid polypeptide, in which a C-terminus of a peptide comprising an amino acid sequence selected from SEQ ID NOs. 1, 2 and 3 is fused to an N-terminus of a helper T cell epitope.

Claim 1 is indefinite for following reasons: First, the limitation “two to eight copies” of Claim 2 lacks antecedent basis for this limitation in Claim 1. Secondly, while dependent claims appear to contain SEQ ID NOs: 1, 2 and 3 in alternative form, Claim 1 presents SEQ ID NO:1, 2 and 3 in combination. Thus, one of ordinary skill in the art cannot be reasonably apprised of the metes and bounds of the invention because it is not clear what forms of hybrid polypeptide is intended. Appropriate correction is required. It is suggested to use Markush phrase “consisting of A, B and C” for cited SEQ ID NOs.

This rejection affects all dependent claims.

7. For the purpose of examination, Claim 1 is interpreted as

Claim 1: An immunogenic hybrid polypeptide, in which ~~a~~ the C-terminus of a peptide is fused to the N-terminus of a helper T cell epitope, wherein said peptide comprising one or more copies of an amino acid sequence selected from the group consisting of SEQ ID NO: 1, 2 and 3. is fused to an N-terminus of a helper T cell epitope.

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Claim Rejections - 35 USC § 112, first paragraph

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding

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each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

10. Claim 11 is directed to a vaccine for preventing or treating obesity, comprising the polypeptide of Claim 1. The scope of the claim is broad, encompassing a vaccine for preventing and treating obesity caused by any causes in any species, including humans. In support of the claim, the specification has shown that the Apolipoprotein B-100 mini-peptides can reduce body weight in mice.

11. “A vaccine” by definition means “a substance used to stimulate the production of antibodies and provide immunity against one or several diseases, prepared from the causative agent of a disease or a synthetic substitute”. Obesity is considered to be a medical condition, caused by multiple factors, including genetic, environmental and medical factors. No vaccine for obesity is currently available in the art. It is not clear in the art which is the key causative agents for obesity. See e.g. Walley, 2009. Thus, it is not predicable in the art if Apolipoprotein B-100 mini-peptides would prevent or treat obesity in all species, especially in humans. Given that Apolipoprotein B-100 is nature host protein humans, the specification has not provided any teaching regarding how providing more Apolipoprotein B-100 mini-peptides would prevent or treat obesity in humans.

12. Because of the empirical and unpredictable nature of the invention with regard to therapeutic treatment, or prophylaxis of obesity, one skilled in the art cannot practice the claimed invention without undue experimentation. The instant invention, based on the

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evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (WO/2002/20040, International Publication date: March 14, 2002) and Punnonen US 6,541,011.

15. Kim discloses Apolipoprotein B-100 mini-peptides comprising SEQ ID NO: 1, 2 and 3, which are 100% identical to the instant SEQ ID NO: 1, 2 and 3. Kim teaches concatemer of peptides comprising two to fifteen copies of SEQ ID NO:1, 2 or 3, see e.g. claims. This teaches the limitation of Claims 1-5, including SEQ ID NO:5, which contains four copies of SEQ ID NO:1. Kim shows that the Apolipoprotein B-100 mini-peptides can reduce body weight in mice, see e.g. Example 6. Kim also explicitly teaches that use of the epitopes of T cells and B cells, specifically from HBV surface antigen, as immune adjuvant for Apolipoprotein B-100 peptides, see e.g. Para 1, page 1.

16. Punnonen teaches multivalent antigenic polypeptide comprising different epitopes, See e.g. line 55-65, col.1; line 29-42, col. 4, and Fig. 16-17. Punnonen teaches a

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HBV Pre-S peptide SEQ ID NO: 10, comprising an amino acid sequence 100% identical to the “epitope” sequence of SEQ ID NO: 7 and 9. see attached sequence alignment

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Apolipoprotein B-100 mini-peptides of Kim by incorporating T cell epitopes, such as T cell epitopes in preS, as suggested and taught by Punnonen and Kim. The skilled artisan would have been motivated to do so, and would have a reasonable expectation of success, given that the Apolipoprotein B-100 mini-peptides has been shown to reduce body weight in mice, and T cell epitopes can enhance immunogenicity of the peptide as taught and suggested by Kim. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-12 of U.S. Patent No. 6,825,318 ('318). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant Claims 1, 10 and 11 are obvious over Claims 1-12 of '318, in view of Punnonen (6,541,011)

19. Claims 1-12 of '318 teaches Apolipoprotein B-100 mini-peptides comprising SEQ ID NOs: 1, 2 and 3, which are 100% identical to the instant SEQ ID NOs: 1, 2 and 3. The '318 explicitly teaches that use of the epitope of T cell, and B cell immune adjuvant of the peptides comprising Apolipoprotein B-100 mini-peptides, see e.g. Para [0038]. The relevance of Punnonen is set forth *supra*. Thus, the claimed polypeptide of Claims 1, 10 and 11 are obvious over Claims 1-12 of '318.

Remarks

20. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648